Appendix D to Part 75—Optional SO_2 Emissions Data Protocol for Gas-Fired and Oil-Fired Peaking Units

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0063; FRL–8867–5]

Etoxazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project #4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 13, 2011. Objections and requests for hearings must be received on or before June 13, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0063. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0063 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 13, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0063, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of May 19, 2010 (75 FR 28009) (FRL–8823–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7675) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the miticide/ovicide etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on peppers, African eggplant, eggplant, martynia, okra, pea eggplant, pepino, roselle, and scarlet eggplant at 0.20 ppm; Crop Group 9: Cucurbit vegetables at 0.20 ppm; Subgroup 13–07A: Caneberry at 1.1 ppm; Subgroup 13–07F: Small fruit vine climbing subgroup except fuzzy kiwi at 0.50 ppm; Subgroup 13–07G: Low-growing berry subgroup at 0.50 ppm and avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, and mamey sapote at 0.20 ppm; and tea at 15 ppm. The petition also proposed to delete the established tolerances in or on strawberry, grape, cucumber, and vegetable, cucurbit subgroup 9A since

they would be covered by the proposed new tolerances. That notice referenced a summary of the petition prepared by Valent, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being set and is setting a subgroup tolerance instead of separate tolerances for some commodities. It was also determined that the proposed deletion of the cucurbit subgroup 9A and establishment of a tolerance for the cucurbit vegetables crop group 9 could not be done due to differences in tolerance levels between subgroups 9A and 9B. Finally, the tolerance expression is being revised to be consistent with current Agency policy. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for etoxazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with etoxazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The existing etoxazole data indicate that it possesses low acute toxicity via all routes of exposure. It is not an eye or dermal irritant or a dermal sensitizer. No toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats.

The liver is the main target organ in mice, rats and dogs. In a 90-day toxicity study in dogs, increased liver weights and centrilobular hepatocellular swelling in the liver were observed. Similar effects were observed in a chronic toxicity study in dogs at similar doses, indicating that systemic effects (mainly liver effects) occur at similar dose levels following short- through long-term exposure without increasing in severity. In a 90-day toxicity study in mice, hepatotoxicity (increased relative liver weight, liver enlargement, and centrilobular hepatocellular swelling) was observed at high doses. Similar effects were observed at the high dose in a mouse carcinogenicity study. Subchronic and chronic toxicity studies in rats produced similar effects (increased liver weights, centrilobular hepatocellular swelling, *etc.*) to those seen in mice and dogs. In addition, slight increases in thyroid weights and incisors were observed in subchronic and chronic toxicity studies in rats at high doses and at terminal stages of the study. Toxicity was not observed at the highest dose tested (HDT) in another carcinogenicity study in mice. There is no evidence of immunotoxicity or neurotoxicity in any of the submitted studies.

Two studies in mice showed no evidence of carcinogenicity up to the HDT. In a rat carcinogenicity study, which was deemed unacceptable due to inadequate dosing, benign interstitial cell tumors (testis) and pancreas benign islet cell adenomas were observed (in females) at the high dose. These effects were not observed in an acceptable carcinogenicity study in rats at higher doses. In special mechanistic male rat studies there were no observable changes in serum hormone levels (estradiol, luteinizing hormone (LH), prolactin and testosterone) or reproductive effects (interstitial cell proliferation or spermatogenesis) noted. EPA classified etoxazole as "not likely to be carcinogenic to humans." Etoxazole is not mutagenic.

The toxicology data for etoxazole provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies. The rabbit developmental toxicity study included maternal toxic effects (liver enlargement, decreased weight gain, and decreased food consumption) at the same dose as developmental effects (increased incidences of 27 presacral vertebrae and 27 presacral vertebrae with 13th ribs). In the 2-generation reproduction study conducted with rats, offspring toxicity was more severe (pup mortality) than parental toxicity (increased liver and adrenal weights) at the same dose, indicating increased qualitative susceptibility.

Specific information on the studies received and the nature of the adverse effects caused by etoxazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2010–0063 in the document titled Etoxazole; "Human Health Risk Assessment for Proposed Tolerances and Uses on Peppers (Bell and Non-bell); Squash/Cucumbers (Subgroup 9B); Avocado; Tropical and Subtropical Fruits (Inedible Peel); Caneberry Subgroup 13–07A; Small Fruit Vine Climbing, Except Kiwifruit, Subgroup 13–07F; Low-growing Berry, Subgroup 13–07G; and Tea," pp. 29–31.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency

estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for etoxazole used for human risk assessment is shown in the following Table:

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETOXAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age and general population including infants and children).	A dose and endpoint attributable to a single dose were not identified in the database including the developmental toxicity studies.		
Chronic dietary (All populations)	NOAEL = 4.62 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.046 mg/kg/day ... cPAD = 0.046 mg/kg/day	Chronic Oral Toxicity Study-Dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver.
Cancer (Oral, dermal, inhalation) ..	Classification: "Not likely to be Carcinogenic to Humans."		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to etoxazole, EPA considered exposure under the petitioned-for tolerances as well as all existing etoxazole tolerances in 40 CFR 180.593. EPA assessed dietary exposures from etoxazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for etoxazole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Surveys for Food Intake by Individuals (CSFII). As to residue levels in food, an unrefined, chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups using tolerance-level residues for all agricultural commodities and 100 percent crop treated (PCT).

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, Cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that etoxazole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for etoxazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of etoxazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of etoxazole for chronic exposures for non-cancer assessments are estimated to be 4.761 parts per billion (ppb) for surface water and 0.318 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 4.761 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Etoxazole is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found etoxazole to share a common mechanism of toxicity with any other substances, and etoxazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that etoxazole does not have a

common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicology data for etoxazole provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies. In a rat reproduction study, offspring toxicity was more severe (pup mortality) than parental toxicity (increased liver and adrenal weights) at the same dose; thereby indicating increased qualitative susceptibility. Based on the concerns in this unit, a Degree of Concern Analysis was performed by EPA, which concluded that concern is low since:

i. The effects in pups are well-characterized with a clear NOAEL;

ii. The pup effects occur at the same dose as parental toxicity; and

iii. The doses selected for various risk assessment scenarios are lower (~3000-fold lower) than the doses that caused offspring toxicity in the rat 2-generation reproduction study. Therefore, the endpoints selected for risk assessment are protective of the effects seen in the rat reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1×. That decision is based on the following findings:

i. The toxicity database for etoxazole is complete except for acute and subchronic neurotoxicity and immunotoxicity studies. Changes to 40 CFR 180.158 make acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200), and immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration. Although these studies are not yet available for etoxazole, the available data do not show any evidence of treatment-related effects on the immune system. Further, there is no evidence of neurotoxicity in any study in the toxicity database for etoxazole. Therefore, EPA does not believe that conducting neurotoxicity and immunotoxicity studies will result in a NOAEL lower than the NOAEL of 4.62 mg/kg/day already established for etoxazole. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no indication that etoxazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility of offspring (pup mortality) compared to less severe parental effects (increased liver and adrenal weights) at the same dose in the rat multi-generation reproduction study, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs (10× for interspecies variation and 10× for intraspecies variation) to be used in the risk assessment. Therefore, there are no residual concerns regarding developmental effects in the young.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to etoxazole in drinking water. These assessments will not underestimate the exposure and risks posed by etoxazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, etoxazole is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to etoxazole from food and water will utilize 11% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for etoxazole.

3. *Short and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short- and/or intermediate-term adverse effect was identified; however, etoxazole is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short- and/or intermediate-term risk is assessed based on short- and/or intermediate term residential exposure plus chronic dietary exposure. Because there is no short- and/or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and/or intermediate-term risk), no further assessment of short- and/or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and/or intermediate-term risk for etoxazole.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, etoxazole is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to etoxazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (gas chromatography/nitrogen-phosphorus detection (GC/NPD) and gas chromatography/mass selective detection (GC/MSD) methods) are available to enforce the tolerance expression. The method may be requested from: Chief, Analytical

Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for etoxazole for the commodities discussed in this document.

C. Response to Comments

EPA received a comment from a private citizen expressing concerns for genetically modified vegetables and undue risks from pesticides. However, this action does not involve use of genetically modified vegetables. Additionally, when new or amended tolerances are requested for the presence of the residues of a pesticide and its toxicologically significant metabolite(s) in food or feed, the Agency, as is required by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), estimates the risk of the potential exposure to these residues by performing an aggregate risk assessment. Such a risk assessment integrates the individual assessments that are conducted for food, drinking water, and residential exposures. Additionally, the Agency, as is further required by section 408 of the FFDCA, considers available information concerning what are termed the cumulative toxicological effects of the residues of that pesticide and of other substances having a common mechanism of toxicity with it. The Agency has concluded after this assessment that there is a reasonable certainty that no harm will result from exposure to the residues of interest. Therefore, the proposed tolerances are found to be acceptable. These assessments consider body residue loads of the pesticide, as well as available information concerning the potential that other substances have a common mechanism of toxicity, in reaching a conclusion as to whether or not the reasonable certainty of no harm decision can be made.

D. Revisions to Petitioned-for Tolerances

Upon review of the data supporting the petition, EPA revised the tolerance for caneberry subgroup 13–07A from 1.1 ppm to 1.5 ppm based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data.

The Agency also corrected the commodity definition from "fruit, small, vine climbing, subgroup 13–07F, except fuzzy kiwifruit" to "fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F."

EPA has also determined that the petitioned-for tolerance on tea at 15 ppm should be established as a tolerance with no U.S. registrations on tea, dried at 15 ppm. At least one U.S. residue field trial study is required to establish a domestic registration on tea; however, no U.S. residue field trial data were submitted in support of the use of etoxazole on tea. Therefore, the Agency has established a tolerance with no U.S. registrations on tea, dried at 15 ppm.

Additionally, IR–4 petitioned for individual tolerances on peppers, African eggplant, eggplant, martynia, okra, pea eggplant, pepino, roselle, and scarlet eggplant (PP 9E7675). In the **Federal Register** of December 8, 2010 (75 FR 76284–76292) (FRL–8853–8), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA retained the pre-existing Crop Group 8 and added a new group titled "Crop Group 8–10 Fruiting Vegetable Group." The new crop group 8–10 added new commodities and created new subgroups (including a subgroup consisting of the commodities requested in PP 9E7675). EPA indicated in the December 8, 2010 final rule as well as the earlier January 6, 2010 proposed rule (75 FR 807) (FRL–8801–2) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing a tolerance on the pepper/eggplant subgroup 8–10B. EPA concludes it is reasonable to establish the tolerance on the newly created subgroup, since the individual commodities for which tolerances were requested are identical to those which comprise the pepper/eggplant subgroup 8–10B.

Also, because of differences in the tolerance levels between subgroup 9A (melon subgroup) and 9B (squash/cucumber subgroup), the two cannot be combined into a single tolerance under Crop Group 9 Cucurbit Vegetables as proposed in the petition. Accordingly, other than the nomenclature change to the existing subgroup 9A tolerance noted below, EPA is leaving the existing subgroup 9A tolerance intact and adding a new tolerance for subgroup 9B. In order to use the correct nomenclature, the existing tolerance for "vegetable, cucurbit subgroup 9A" is being re-named "melon subgroup 9A."

Finally, EPA has revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of etoxazole not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on pepper/eggplant subgroup 8–10B at 0.20 ppm; tea, dried at15 ppm; berry, low growing, subgroup 13–07G at 0.50 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.50 ppm; squash/cucumber subgroup 9B at 0.02 ppm; avocado at 0.20 ppm; papaya at 0.20 ppm; star apple at 0.20 ppm; sapote, black at 0.20 ppm; mango at 0.20 ppm; sapodilla at 0.20 ppm; canistel at 0.20 ppm; sapote, mamey at 0.20 ppm; and caneberry subgroup 13–07A at 1.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 1, 2011.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.593 is amended by:
■ i. Revising the introductory text in paragraph (a);
■ ii. Removing the commodities "Cucumber," "Grape" and "Strawberry" from the table in paragraph (a);
■ iii. Revising the entry "Vegetable, cucurbit subgroup 9A" to read "Melon subgroup 9A" in the table; and
■ iv. Alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.593 Etoxazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of etoxazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only etoxazole (2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole) in or on the commodity.

Commodity	Parts per million
* * * * *	
Avocado	0.20
Berry, low growing, subgroup 13–07G	0.50
Caneberry subgroup 13–07A	1.5
Canistel	0.20
* * * * *	
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.50
* * * * *	
Mango	0.20
Melon subgroup 9A	0.20
* * * * *	
Papaya	0.20
Pepper/eggplant subgroup 8–10B	0.20
* * * * *	
Sapodilla	0.20
Sapote, black	0.20
Sapote, mamey	0.20
* * * * *	
Squash/cucumber subgroup 9B	0.02
Star apple	0.20
* * * * *	
Tea, dried*	15
* * * * *	

*There are currently no U.S. registrations for tea as of April 13, 2011.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0274; FRL–8868–4]

Escherichia coli O157:H7 Specific Bacteriophages; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria when applied/used on food contact surfaces in food processing plants in accordance with the terms of Experimental Use Permit (EUP) No. 74234–EUP–2. Intralytix, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria. The temporary tolerance exemption expires on April 1, 2013.